REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments, claims 49 and 75 are cancelled, claims 46, 50, 51, 62, 67-69 and 74 are amended and claims 76 and 77 are added, whereby claims 46-48, 50-74, 76 and 77 will be pending, with claims 46, 68 and 74 being independent claims.

Support for the new claims can be found throughout the present specification and in the cancelled claims.

Applicants emphasize that the amendments to claims 46, 50, 51, 67-69 and 74 are without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute the amended claims in their original, unamended form in one or more continuation and/or divisional applications.

It further is noted that entry of the present amendments is proper in that they do not raise any new issues and do not require a further search. For example, the ratios of (a) and (b) in the amended independent claims have already been considered by the Examiner.

Summary of Office Action

As an initial matter, Applicants note with appreciation that the Examiner has withdrawn all rejections which are set forth in the previous Office Action.

(Presumably) claim 62 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 46-61 and 64-75 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO/2003/039505, cited in the instant Office Action as the alleged English equivalent, Bankowski et al., U.S. Patent No. 7,294,330 (hereafter "BANKOWSKI").

Claims 62 and 63 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI in view of US Patent Publication 2002/0077372 (hereafter "GERS").

Claims 46-56, 64-70 and 72-75 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shen, U.S. Patent No. 6,042,816 (hereafter "SHEN"), in view of Yu et al., U.S. Patent No. 5,571,841 (hereafter "YU").

Claims 57-63 and 71 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU in further view of GERS.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested, in view of the foregoing amendments and the following remarks.

Response to Rejection under 35 U.S.C. § 112, Second Paragraph

(Presumably) claim 62 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner appears to take the position that the phrase "wherein the microemulsion is obtainable by" renders claim 62 indefinite and suggests that "obtainable by" by replaced by "obtained by".

Applicants respectfully (and strongly) disagree with the Examiner in this regard. However,

in order to facilitate and expedite the prosecution of the present application, claim 62 has been amended as suggested by the Examiner, thereby rendering this rejection moot.

Response to Rejections of Claims under 35 U.S.C. § 103(a) over BANKOWSKI as Primary Document

Claims 46-61 and 64-75 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI and claims 62 and 63 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI in view of GERS. The rejection essentially alleges that with the exception of claims 62 and 63 the elements of the rejected claims are either disclosed or rendered obvious by BANKOWSKI and that the elements recited in claims 62 and 63 are rendered obvious by GERS. The Examiner concedes that BANKOWSKI fails to disclose "an example wherein the claimed components, at the claimed percentages are combined into a single composition" but alleges that BANKOWSKI teaches "that all of the claimed components may be combined into a composition within the claimed percentage ranges".

Applicants respectfully traverse these rejections. In particular, it is noted that BANKOWSKI is directed to the use of selected β-glucuronidase-inhibiting substances in a cosmetic deodorant or antiperspirant composition for reducing the body odor caused by decomposition of steroid esters (see, e.g., col. 1, lines 16-19 of BANKOWSKI). According to BANKOWSKI, suitable β-glucuronidase-inhibiting substances are the hundreds of substances of most diverse structures which are set forth in, e.g., col. 2, lines 8-65 thereof and are further discussed in the passage from col. 2, line 66 to col. 9, line 32.

BANKOWSKI further discloses that cosmetic deodorant compositions which contain a selected β-glucuronidase-inhibiting substance may contain various other, non-essentential

components such as the hundreds of fat substances, non-polar or polar liquid oils, water-soluble alcohols, hydrophilically modified silicones, surface-active substances, lipophilic coemulsifiers, antiperspirant active compounds and additional deodorants (fragrances, antimicrobial, antibacterial or germ-inhibiting substances, antioxidants or odor absorbents), complexing substances, thickeners and further cosmetically and dermatologically active substances which are disclosed in the passage from col. 10, line 56 to col. 18, line 6, of BANKOWSKI.

Applicants submit that in view of the foregoing facts the disclosure of BANKOWSKI encompasses thousands, if not millions, of possible combinations of (i) β-glucuronidase-inhibiting substances and (ii) non-essential components.

In the absence of any guidance whatsoever in BANKOWSKI as to which specific combinations are of advantage, there is no basis for the assumption that in view of the disclosure of BANKOWSKI one of ordinary skill in the art would be prompted to provide a composition which comprises both mandelic acid (as β-glucuronidase-inhibiting substance) and an aluminum compound and in particular, an activated aluminum compound as antiperspirant, let alone in the ratios recited in the instant independent claims.

In this regard, the Examiner is reminded that the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has "decline[d] to extract from *Merck* [*& Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that... regardless of how broad, a disclosure of a

chemical genus renders obvious any species that happens to fall within it."). See also *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995). See also MPEP 2144.08.

In the present case there is nothing in BANKOWSKI which would cause one of ordinary skill in the art to specifically select a combination of mandelic acid and an antiperspirant and in particular, an (activated) aluminum compound from the thousands of possible combinations encompassed by the disclosure of BANKOWSKI. For example, even if an aromatic carboxylic acid having 6-20 carbon atoms were to be selected as β-glucuronidase-inhibiting substance, according to col. 5, lines 7-8 of BANKOWSKI the preferred acids would be rosemary acid, ferulic acid and parahydroxymandelic acid sodium salt.

Further, while activated aluminum chlorohydrates are mentioned in passing in col. 15, lines 58-61 of BANKOWSKI, there is no suggestion that these activated chlorohydrates offer any advantage over their "regular" counterparts.

Even further, the Examiner's attention is directed in particular to the following passages of the present specification (page 4, line 6 to page 5, line 8 and page 7, lines 1-25):

> In order to achieve an increased antiperspirant effectiveness of classic aluminum chlorohydrate (ACH) solutions, these are thermally treated depending on concentration, temperature and pressure, and the resulting solutions are dried by means of spray-drying.
>
> This leads to an increased amount of smaller molecule sizes being present in stable form. However, these activated aluminum complex salts (AACH) effective as antiperspirant disintegrate in water back to their original equilibrium state, meaning that in aqueous preparations increased effectiveness is lost.
>
> Use of these activated ACH types (AACH) has therefore hitherto only made sense in nonaqueous systems since otherwise reconversion to the molecule size distribution as occurs in classic ACH solutions is possible, as described, for example, in the article by A. H. Rosenberg – Antitranspirant Technology, SÖFW-Journal, 128 (4) 2000.
>
> It is therefore an object of the present invention to provide an aqueous preparation which has an increased antiperspirant effectiveness without the described disadvantages. In particular, it

is therefore the object to provide aqueous cosmetic preparations which, despite the water content, have an increased antiperspirant effectiveness as a result of the addition of activated aluminum complex salts.

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It was surprising and unforeseeable by the person skilled in the art that a cosmetic formulation comprising at least one activated aluminum compound effective as antiperspirant, at least one α-hydroxycarboxylic acid and water permits the provision of a transparent and low-stick cosmetic antiperspirant preparation.

Through the combination of activated aluminum compounds effective as antiperspirant, in particular activated aluminum chlorohydrate (AACH), and at least one α-hydroxycarboxylic acid, preferably mandelic acid, it is possible to prepare aqueous, preferably also transparent cosmetic preparations.

Use of the activated ACH types (AACH) has therefore hitherto only made sense in nonaqueous systems since otherwise reconversion to the molecule size distribution as occurs in classic ACH solutions is possible.

By adding α-hydroxycarboxylic acid, in particular mandelic acid, this reconversion is now surprisingly avoided.

It is assumed that complex formation, for example AACH-mandelic acid, is the cause of this effect.

Thus, a chelate complex could form through aluminum with the alpha-hydroxy group and the acid hydroxy group of mandelic acid with the release of protons. This complex is very stable. Furthermore, the bonding to these two hydroxy groups explains why a gelling according to the invention was observed in the case of mandelic acid.

In addition, the phenyl radicals of mandelic acid can aggregate via the van der Waals forces, thus producing a framework.

In addition, the liberated protons could break open the Al complex, as a result of which water may be incorporated into the helix-like structures of the AACH.

It is decisive that through the combination of α-hydroxycarboxylic acid, in particular mandelic acid, and activated ACH in aqueous media, no destruction of the activation of any kind is observed.

The above statements regarding the lack of stability of activated aluminum antiperspirant salts in aqueous media are confirmed by, e.g., col. 1, lines 14-30 of SHEN.

In other words, the presence of mandelic acid in compositions which comprise an activated aluminum antiperspirant compound and water surprisingly makes it possible to stabilize the activated aluminum compound against decomposition into a "regular" aluminum compound and thus preserves the increased antiperspirant activity of the activated aluminum compound compared to a "regular" aluminum compound (in this regard see, e.g., bottom of page 10 and top of page 11 of the present specification). BANKOWSKI (and GERS) do not contain the slightest suggestion in this regard, and for this reason alone, are unable to render obvious the subject matter of any of the claims submitted herewith.

Applicants submit that for at least all of the foregoing reasons, the rejection of claims 46-61 and 64-75 under 35 U.S.C. § 103(a) over BANKOWSKI (and the rejection of dependent claims 62 and 63 under 35 U.S.C. § 103(a) over BANKOWSKI and GERS) are unwarranted and should be withdrawn, which action is respectfully requested.

Response to Rejections of Claims under 35 U.S.C. § 103(a) over SHEN as Primary Document

Claims 46-56, 64-70 and 72-75 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU and claims 57-63 and 71 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU in further view of GERS. The rejection asserts, *inter alia*, that SHEN teaches compositions comprising enhanced antiperspirant salts, which allegedly reads on activated antiperspirants, alpha hydroxycarboxylic acids, and water.

The Examiner concedes that SHEN does not teach mandelic acid as hydroxycarboxylic acid but alleges that YU cures this deficiency of SHEN. In this regard, the rejection essentially asserts that YU would have rendered it obvious to one of ordinary skill in the art to produce the formulations of SHEN with mandelic acid as hydroxycarboxylic acid. One of ordinary skill in the art would allegedly have been motivated to do so "because [SHEN] teaches antiperspirant compositions comprising hydroxycarboxylic acids and [YU] teach[es] that alpha-hydroxycarboxylic acids, such as mandelic acid, may be added to antiperspirant formulations to increase efficacy". Page 10, last paragraph of instant Office Action.

Applicants respectfully traverse these rejections as well. In particular, while the title and the claims of YU expressly mention mandelic acid (for use in a method of treating wrinkles), the specification of YU does not emphasize mandelic acid at all, let alone conveys the impression that mandelic acid is a particularly desirable hydroxy acid. For example, mandelic acid is not mentioned in any of the 29 Examples of YU. Neither does the list of more than 30 "representative" hydroxy acids in col. 6, lines 24-40 of YU include mandelic acid (although it includes five derivatives of mandelic acid).

Even further, it is not seen that the property of mandelic acid which is highlighted in YU, i.e., its ability to visibly reduce human skin wrinkles (see, e.g., claim 1 of YU), provides any reason for one of ordinary skill in the art to add mandelic acid to the anti-perspirant preparations of SHEN. In particular, antiperspirant preparations are applied to the axilla (see, e.g., col. 14, lines 39-44 of SHEN). Clearly, wrinkle reduction at the axilla is not associated with any apparent benefit. For the above reasons alone, YU is unable to render it obvious to use mandelic acid as hydroxycarboxylic acid for the purposes taught by SHEN.

Additionally, even if one were to assume, *arguendo*, that one of ordinary skill in the art would be motivated to combine the teachings of SHEN and YU for any reason, it is not seen that he or she would use mandelic acid as hydroxycarboxylic acid in the enhanced antiperspirant salts of SHEN.

In particular, the passage of SHEN relied on by the Examiner in this regard, col. 6, lines 45-62, states (emphasis added):

> The compositions of the present invention also contain a water soluble amino and/or hydroxy acid which is effective in increasing and/or stabilizing the HPLC peak 4:3 area ratio of the antiperspirant salt. Such acids include amino-and/or hydroxy-substituted lower alkanoic acids (including substituted derivatives thereof), preferably where the amino or hydroxy group is located on the α-carbon (i.e. the same carbon to which the carboxy group is attached). The lower alkanoic acid will generally have 2 to 6, preferably 2 to 4, carbon atoms in the alkanoic acid chain. Typical amino and/or hydroxy substituted lower alkanoic acids include any of the amino acids such as glycine, alanine, valine, etc. and hydroxy acids such as glycolic acid and lactic acid. These amino and/or hydroxy substituted lower alkanoic acids may also contain various substituents which do not adversely affect their activity. The preferred amino and/or hydroxy substituted lower alkanoic acids are glycine, alanine, and glycolic acid, with glycine being most preferred.

Accordingly, the hydroxycarboxylic acids which are to employed according to SHEN are hydroxy substituted lower alkanoic acids, preferably alkanoic acids having from 2 to 4 carbon atoms in the alkanoic acid chain. This clearly excludes an araliphatic acid such as mandelic acid (having a total of 8 carbon atoms).

One of the reasons why SHEN excludes araliphatic acids such as mandelic acid as hydroxycarboxylic acids may be the fact that SHEN also requires the use of a **soluble** calcium salt (see, e.g., claim 1 of SHEN). However, as can be taken from, e.g.,

http://books.google.com/books?id=Owuv-c9L_IMC&pg=PA618&lpg=PA618&dq=soluble+%22calcium+mandelate%22&source=bl&ots=zVs

_sjTcb&sig=tcChVCOYa24E3XvLMZx1OVO7L9c&hl=en&ei=gi44Sue9F9CptgeA3tXiDA&sa=X&oi=book_result&ct=result&resnum=3

calcium mandelate is only slightly soluble in water. This is confirmed by, e.g., the disclosure of U.S. Patent No. 4,239,912 (which is entitled "Process for resolving DL-Mandelic acid with novel 2-benzylamino-1-butanols"). In the passage from col. 6, line 55 to col. 7, line 5 this patent states (emphasis added):

Racemization and Recovery of DL-Mandelic Acid

The alkalized aqueous phase from (2) which contains the sodium or potassium salt of the undesired mandelic acid is further alkalized by the addition thereto of about two moles of additional sodium or potassium hydroxide per mole of mandelic acid therein. The reaction mixture is then heated at reflux until racemization is completed, as indicated by a zero optical rotation. The reaction mixture is then neutralized to pH 7 by the addition of concentrated hydrochloric acid and at least an equivalent amount of calcium chloride is added. The resulting calcium DL-mandelate which precipitates is recovered by filtration, washed with water and reacted in water with an equimolecular amount of sodium carbonate. The precipitated calcium carbonate is recovered by filtration and the resulting filtrate containing sodium DL-mandelate is acidified, as previously described, and recycled in (1).

In the passage from col. 9, line 35 to col. 10, line 4 this patent further states (emphasis added):

EXAMPLE 4

Racemization of Sodium L-(+)-Mandelate

The aqueous solution of sodium L-(+)-mandelate from Example 1 is mixed with 45 mls of 50% aqueous sodium hydroxide, heated to boiling and concentrated to about 1100 mls, then refluxed for 20 hours. At the end of this period the sodium L-(+)-mandelate is completely racemized; $[\alpha]_D^{25} = 0°$ (C, 4 in water).

The solution is then neutralized to pH 7 by adding concentrated hydrochloric acid thereto, and reacted at 50° C. by slowly adding a solution of calcium chloride monohydrate (33 grams; 0.255 mole) in 20 mls of water. The resulting reaction mixture is cooled to 25° C. and filtered to recover the solid. The recovered solid is washed free of chloride ion with water and dried to obtain 79 grams (92.3% of theoretical) of calcium D, L-mandelate.

Accordingly, using mandelic acid in water in combination with a water-soluble calcium salt results in the precipitation of calcium mandelate. This is a disincentive rather than a motivation to use mandelic acid for the purpose disclosed in SHEN and is yet another reason why one of ordinary skill in the art would not use mandelic acid as hydroxycarboxylic acid in the stabilization process disclosed by SHEN.

Applicants submit that for at least all of the foregoing reasons, SHIN in view of YU (and GERS) fails to render obvious the subject matter of any of the claims submitted herewith. In view thereof, withdrawal of the rejection of claims 46-56, 64-70 and 72-75 under 35 U.S.C. § 103(a) over SHEN in view of YU and the rejection of dependent claims 57-63 and 71 under 35 U.S.C. § 103(a) over SHEN in view of YU and GERS is clearly warranted as well and thus respectfully requested.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, wherefore an early issuance of the Notices of Allowance and Allowability is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
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